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No.

In the Supreme Court

OF THE

United States

OCTOBER TERM, 1986

GEOFFREY A. DI BELLA, M.D.,
Petitioner,

vs.

UNITED STATES OF AMERICA,
Petitioner.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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QUESTIONS PRESENTED

1. May a physician who acts without any criminal intent in prescribing a controlled substance drug be found guilty of a felony crime?

2. May a physician be convicted of unlawful distribution of controlled prescription drugs, in relation to his writing of prescriptions for the controlled drug, without an instruction to the jury that the circumstances they are to consider relate to each act of prescribing?

LIST OF PARTIES

The parties in this case are Geoffrey A. Di Bella, M.D., and the United States of America, as shown in the caption. This Petition does not concern the other persons who were Defendents in the case.

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Petitioner, Geoffrey Di Bella, M.D., respectfully prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Second Circuit, affirming the judgment of conviction entered against him by the United States District Court for the Southern District of New York.

OPINIONS BELOW

The opinion of the Court of Appeals, not officially reported, appears in the appendix hereto at pp. A1-A4.

JURISDICTION

The Judgement of the Court of Appeals was entered on November 19, 1986 and the request for re-hearing was denied on January 15, 1987. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS

The statutes involved are 21 United States Code, Sections 802, 822, and 841. Also, involved is 21 Code of Federal Regulation § 1306.04(a). The pertinent parts of the statutes and Regulation are set forth in the appendix, part C.

STATEMENT OF THE CASE

Following its own recent precedent, *United States v. Vamos*, 797 F.2d 1146 (2d Cir. 1986), the Second Circuit held in this case that "'good faith medical practice' in the context of the federal drug control laws is determined by objective standards and does not involve a defendant's subjective state of mind". Thus this case presents the question whether a physician who prescribed controlled drugs in the genuine good faith belief that he was acting in accordance with accepted professional standards can be punished as a drug dealer because his practice, judged by objective standards, allegedly fell short of the highest level of professional medical practice.

Dr. Geoffrey A. Di Bella is a physician who has been licensed to practice medicine in the state of New York since 1967. Dr. Di Bella's specialty is psychiatry, and he has practiced the specialty with distinction, achieving the status of a Fellow of the American Psychiatric Association and serving as Clinical Associate Professor of Psychiatry at New York Medical College. Other than the indictment in this case, no complaint or charge of professional misconduct or malpractice ever has been filed against him.

The Charge and the Results

In December 1984, however, Dr. Di Bella was indicted for conspiracy to distribute and two substantive counts of distribution of methaqualone ("quaaludes")[1] a "Schedule II" controlled

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[1] Methaqualone, which also has the trade name quaalude, is a sleeping pill.

substance.[2] The indictment, which named eight defendants in various combination of counts, concerned the activities of an organization called Jorum, which the government alleged served as fronts for the distribution of quaaludes. Dr. Di Bella was one of five physicians named in the indictment, each of whom worked for various periods at the clinical facilities run by Jorum in he City of New York. Following a jury trial, Dr. Di Bella was acquitted of conspiracy, but convicted of the distribution counts. He was sentenced to concurrent sentences of two years' imprisonment, to be followed by two years of special parole, and a $5,000.00 fine.

Substantial Evidence Supported Defense

Throughout the litigation, Dr. Di Bella asserted that he had acted in good faith according to his best understanding of proper standards of medical practice. Substantial evidence supported this claim.

First, it was undisputed that Dr. Di Bella did not organize or direct the clinics, or create their policies or procedures. Nor did he have any financial stake in the clinics. He worked with Jorum in response to an advertisement in the New York Times, and this lasted ten days (this was usually one day a week over a three month period). During most of this time he was paid a flat fee of $3,000.00 per day to see patients.

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[2] Most hypnotics—also referred to as tranquilizers and sleeping pills—are controlled substances and are on Schedules set out by the Drug Enforcement Administration. The schedules are a theoretical assessment of potential for abuse and range from Schedule V to Schedule I. 21 U.S.C. § 812. The lower the schedule number the greater the potential for abuse (though it isn't particularly clear as to what the abuse potential difference actually is between each of the Schedules). Schedule II is defined in the statute as approved and recognized for treatment, though it has a high potential for abuse. The drugs may change categorization and subsequent to the event alleged in this case Quaalude was removed from Schedule II and placed on Schedule I. Consequently, it may no longer be used for treatment except in specially approved circumstances.

Second, it was undisputed that in his own practice and at the clinic Dr. Di Bella carried out all of the standard procedures common to all physicians engaged in a genuine effort to treat patients' physical and emotional complaints in accordance with accepted medical procedure. Even though the practice at Jorum involved seeing a large number of patients, Dr. Di Bella kept careful records on each patient, spent time examining and conferring with each patient, and saw each patient only after each one had completed an extensive questionnaire and been thoroughly examined by a qualified physician's assistant. Moreover, it was undisputed that during the brief time he was working in this insomnia practice, Dr. Di Bella sought to improve the medical service he thought he was providing—he introduced forms and practices used by leading authorities on insomnia, and continually edited those forms, as well the ones already in use.

Third, there was a complete absence of any testimony suggesting that Dr. Di Bella had ever given the slightest indication to anyone that he believed the practice at the clinic was anything other than legitimate. Thus there was no evidence that Dr. Di Bella was an "insider" participant in discussions acknowledging that the clinic's operations were designed to make money by charging patients high fees[3] for quaalude prescriptions. Neither insider witnesses nor former patients of the clinics provided incriminating evidence. Even undercover government agents who had visited the clinic, feigned insomnia symptoms, and been treated by Dr. Di Bella, could not testify that Dr. Di Bella had ever performed in a manner inconsistent with the normal practice of medicine or had ever given any indication that he regarded his medical practice as a sham or front. In fact, all the witnesses who worked with Dr. Di Bella and actually observed him, only could report he was very professional in his conduct.

Finally, it was undisputed that the clinic's operators maintained a sophisticated organization directed to persuading not only outside investigators but also the doctors that came to work with

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[3] While the fee, which ranged from $150.00 to $200.00, may have been high, it was not an indication of wrongdoing as it had no relation to the number of pills which may have been prescribed.

them. In Dr. Di Bella's case they explained to him they were innovative experts in the management of highly specialized medical practices. Further, attorneys had been employed and gave assurances that there were no improprieties. The operators of the clinics thus took pains—except, perhaps among themselves—to give every appearance of legitimacy.

Trial Corrupted Good Faith Defense

The trial of the case, however, was not designed to provide a fair test of Dr. Di Bella's assertion of good faith. First, the trial was a trial of four doctor defendants who had worked at the clinic at different times. It was undisputed that none knew or worked with the other. The jury was thus encouraged to judge the clinic operation as a whole, rather than to focus on the guilt of particular individuals. Dr. Di Bella's motion for severance was denied.

Second, the charges against Dr. Di Bella were erroneously formulated to direct the jury's attention away from the question of the doctor's intent at the time of the writing of any particular prescription.[4] The legal principle in this situation is clear—in determining if unlawful distribution took place the evaluation should be what occurred in relation to a particular prescription. However, the counts on which Dr. Di Bella was convicted duplicitously lumped together claims that Dr. Di Bella had unlawfully prescribed 33,420 and 5,812 doses of quaaludes over three and four month periods respectively. The jury instructions did not clarify the situation. Nor did the trial make apparent what evaluation was required—the particular circumstances of only a handful of those prescriptions were the subject of the testimony, and in none of them was there evidence that Dr. Di Bella indicated any subjective intent other than to treat a patient's legitimate medical problems. Dr. Di Bella's attack on the duplicitous and misleading counts[5] was rejected.

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[4] A copy of the counts complained of in the indictment are found in the Appendix, Part D.

[5] The indictment's language went even further than lack of focus on an individual prescription in taking attention away from the person's intent. In conformity with the objective analysis it implied should be

Third, evidence bearing on Dr. Di Bella's intent was excluded. Testimony tending to prove that the fee he received would be believed by him as reasonable compensation for a doctor for a 12-hour day of seeing patients was not received. This left the jury to speculate that Dr. Di Bella may have received excessive pay because of the illegality of his actions.

Fourth, the Expert testimony emphasized the over-all practice of what they understood was the method followed at Jorum. None of the three experts noted any specific item that they found in Dr. Di Bella's records that indicated a criminal intent, or even a failure to follow acceptable medical standards. None of the experts carefully reviewed any particular prescription and said that the medical records were inappropriate, or what was done was inappropriate if the patient's complaint was believed. Moreover, they were allowed to use, over objection, the term "good faith" thereby adding to the confusion of what standard the jury was to follow in making a determination. Once again, the thrust of the evidence tended not to convict Dr. Di Bella personally, but convict him by the overall operation of the clinic, and by the innuendos therefrom.

Finally, the fairness of the trial was brought into further question by the thoroughly unprofessional conduct of the prosecutor, whose persistent denigration and threatening behavior toward the defense attorneys (including warning one attorney that he was "not a defendant, yet" and throwing water on another) evoked the censure of the trial judge and led the Court of Appeals to forward the trial record to the grievance committee for investigation.

In these circumstances, the trial judge's charge was of central, critical importance to the possibility of a fair inquiry by the jury. But despite Dr. Di Bella's request for language that made clear

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made, the language "caused to be distributed" was used—as if whether he intended the act to occur was not relevant. In addition a specific number of prescriptions was not even named. The indictment stated "approximately" instead. Besides the emphasis on an "objective" view of the case that the use of the word "approximately" causes, this petitioner submits it is fundamentally incorrect that a person may be "approximately" guilty of a crime.

that a physician could only be convicted of a controlled substance offense if he had criminal intent—that is, if his intent was to dispense drugs for non-medical purposes, rather than in a good faith effort to practice medicine—a correct instruction was not given. Instead, the following instruction was given:

> "If a doctor dispenses a drug in good faith in medically treating a patient, doctor has dispensed the drug for a legitimate purpose in the usual course of medical practice; that is, he has dispensed the drug lawfully.
>
> Good faith in this context means good intentions and the honest exercise of *the best* professional judgment as to the patient's needs. It means the doctor acted in accordance with what he *reasonably* believed to be proper medical practice." (Tr. p. 3528, emphasis added)

Thus the District Court's instructions—particularly the word "reasonably"—were confusing on the issue of how an evaluation was to be made, and, in fact, permitted the jury to convict if the doctor's practices, objectively viewed, failed to conform to accepted medical practices[6].

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[6] An over-all viewing of the jury instructions confirms that it was an objective standard that was intended to be provided by the Trial Court and that is how it would have been understood by a juror. Thus the Second Circuit's approval of the case is an approval of this objective approach. An analysis of what occurred at trial makes this clear.

First, a definition of specific intent was not given. This may have led them to follow a subjective evaluation. Furthermore, such an instruction was given in relation to the conspiracy charge. Thus since it was not given in relation to the distribution counts, the import was that unlike the conspiracy charge, a criminal intent is not required on the distribution counts.

Secondly, the judge read the statute. (Tr. 3525; 21-23) The language therein does not reveal any mens rea requirement. It's use of intent probably would be understood that the act was done voluntarily.

Third, a reading of the indictment was done (TR. 3525); its plain meaning to a layman would be a strict liability concept. Also, as stated in an earlier footnote, the use of the words "caused to be" implies that criminal intent is not required. As brought out in the text of this Petition, the prescriptions were all lumped together as if individual

Another error caused by this allowance of an objective view is the failure to instruct the jury to consider the circumstances relating to the writing of each (or at least one) prescription.

The Court of Appeals rejected Dr. Di Bella's various assertions of error. The Court held that claims going to Dr. Di Bella's good faith were without merit because of the *Vamos* (supra) case.[7] In effect, the court ruled that Dr. Di Bella's entire defense was beside the point. So long as his dispensing of drugs was objectively out of keeping with the generally accepted practices of the medical profession, his subjective intent to practice responsibly was held irrelevant to his criminal liability. Malpractice—the mere failure to attain a certain standard of competence—now has been defined as a federal crime.

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actions were not important. Finally, as stated in an earlier footnote, the use of "approximately" again detracts from the necessity of making a personal evaluation. Over objection the indictment also was given to the jury.

Fourth, the Judge gave a conscious avoidance instruction. In doing so the Court said, "you may consider whether a defendant deliberately closed his eyes to what otherwise *should* have been obvious to him or her". The use of "should" implies the doctor was required to know something and again supports an objective approach. (The giving of this instruction was not supported by any evidence, and therefore done in error. Further, if given properly the word "would" should have been used instead of "should").

Fifth, not only did the "good faith" instruction use the word "reasonably", in addition, the word "the" was inserted changing the meaning and conversational tone of "best" (itself not a word that should have been used but one that has been found allowable and implies a belief in what one was doing). Thus the change caused was to an objective standard of behavior of highest expectation, "the best".

[7] The Appellate Court made no direct ruling on the jury instructions' lack of specifity in evaluating each prescription despite the misleading language in the indictment.

REASONS FOR GRANTING THE WRIT

I

THE STANDARD BY WHICH A DOCTOR MAY BE CONVICTED IS OF FUNDAMENTAL IMPORTANCE TO THE PRACTICE OF MEDICINE

The Court below has ruled that a medical doctor may be convicted of a felony that carries severe penalties and enormous social stigma—the crime of distributing drugs—without any regard to the doctor's intent. Even if it is clear that a doctor had a good faith belief that in prescribing a controlled substance he was acting in accordance with proper medical procedures, his action is a crime, according to the Second Circuit, if, as determined, after the fact by alleged "objective standards", the prescription was not properly written.

The interpretation of this law—Title 21 of the United States Code, section 841—therefore has great importance. This law not only affects unscrupulous drug dealers it affects hundreds of thousands of medical doctors. In addition it affects millions of other health professionals like pharmacists, dentists, osteopaths, and nurses. The prescribing of those drugs which are controlled substances easily occurs over 100 million times per year. Physicians need—and 5th Amendment Constitutional Due Process mandates—society to inform them clearly about what the law requires.

An explanation is essential not only because of the number of people involved, but the nature of the activity. A wide latitude is necessary for the effective practice of medicine.[8] It is fundamentally recognized in our society that there are legitimate differences in opinion about the proper medical treatment in particular cases. There are numerous reasons for this. Different people respond differently to treatment methods. Doctors may disagree in scien-

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[8] It has been recognized that there is a constitutionally protected privilege and freedom in practicing medicine in that a doctor is invested with a discretionary authority in his decision-making because of the trust given his position and because of the licensing requirements he has met. *Doe v. Bolton*, 410 U.S. 179, 93 S.CT. 739, 35 L.Ed.2d 201 (1973).

tific terms about a diagnosis. Doctors may also disagree with the scientific basis for the method of treatment. Furthermore, medicine is still such an art that these disagreements usually are acceptable. Finally, not only are these differences helpful in providing adequate medical treatment to the population, but it encourages research to take place to advance the science of medicine.

Were the decision of the Second Circuit allowed to stand, then the Constitutional concepts of proper warning and equal protection would be placed askew, and doctors could no longer be confident in respondintg to a patient's needs.

Instead doctors would have to fear that a prosecutor who disapproves of the doctor's practice may prosecute him for a serious criminal violation. This fear could well lead to doctors to restrict their practices to only the most conventional methods, or even to refuse to treat many cases altogether. They wouldn't want to find themselves in a trial where their practice is governed by what the prosecutor and his experts declare is appropriate practice. They wouldn't want to find themselves in front of a judge and jury who didn't care whether the doctor genuinely believed what he was doing was lawful and medically correct; and, therefore they wouldn't want to find themselves convicted and in jail notwithstanding their good faith belief. And, of course, they shouldn't have to be placed in that position. As stated in *U.S. v. Moore,* 423 U.S. 122, 96 S.Ct. 335, 46 L.Ed.2d 333 (1975), violations are not to depend on the whim of the prosecutor.

Undoubtedly there need to be, and are, controls on the medical profession. This court in *U.S. v. Moore* (supra) already has made clear that a doctor may not simply declare anything he wishes to be a standard of practice and thereby give himself immunity from prosecution. However, if new rulings change what is considered a felony crime, it shouldn't be something the Appellate Courts fashion capriciously.

Indeed this Court has already formulated a fundamental, basic rule—it will be presumed that Congress requires unlawful intent

of a felony crime[9] unless Congress explicitly states otherwise. *Liparota v. United States,* 471 U.S. ____, 85 L.Ed. 434, 105 S.Ct. 434 (1985). Surely our society must afford the same protections to a doctor as it gives to a "street dealer". It is fundamental, black-letter law, and law essential to constitutional protections of due process under the 5th Amendment, that in crimes involving imprisonment "an act does not make one guilty unless his mind is guilty".[10] Consequently, if there now is going to be an exception to these fundamental principles this is an important enough issue—effecting as it does so many people in a common occurrence in their livelihood—that it deserves the attention of the nation's highest court.

THE SUPREME COURT SHOULD GRANT CERTIORARI BECAUSE THERE IS CONFLICT BETWEEN THE CIRCUITS IN HOW TO EVALUATE WHETHER A PHYSICIAN'S CONDUCT IS "IN THE COURSE OF PROFESSIONAL PRACTICE".

Introduction

The Supreme Court review of this case would eliminate the conflicts between the circuits and also would clarify the meaning of the law. The decision below conflicts with decisions from other federal Courts of Appeals in three distinct ways. First, the Second Circuit has announced, in this decision and in its prior *Vamos* opinion (supra), a legal test for ciminal liability that is at variance with the standards set forth by at least four other circuits. Second, the language approved for a jury instruction in the Second Circuit follows its interpretation of the law and conflicts with language used in at least three other circuits. Third, the Second Circuit has affirmed a conviction on a factual record that contains none of the indicia of lack of legitimate medical practice that have been

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[9] There is no doubt that Congress did not intend this statute to be a quasi-civil as the offense allows imprisonment up to 5 years and a fine up to $15,000.00. The potential penalties were increased in 1984 to a 15 year term of imprisonment and $125,000.00 fine

[10] W. LaFave and A. Scott: Handbook of Criminal Law, West Publishing Company, St. Paul, Minnesota, 1972 pp. 192 and 222-23.

regarded by other courts as the minimum basis for liability under the statute. In other words there is a conflict in interpreting the sufficiency of the evidence.

Description of Basic Conflict

The crux of the problem arises in determining how to evaluate the phrase, "in the course of professional practice". This dispositive phrase indicates the circumstances which exempt a physician from prosecution. Furthermore, the term, "good faith" often is used to describe behavior that is considered appropriate and therefore "in the course of professional practice". The lack of complete definitions for those terms, either in the statute (21 U.S.C. 841, 802) or caselaw, has caused confusion and complicated interpretation. This has lead to the basic conflict. This Court must now resolve which one of two views is the applicable law in judging a doctor's conduct: the person's state of mind, which in this situation means determining whether there was an intent by the doctor to act within the law and in accordance with what he believed to be acceptable medical principles—a subjective analysis—or instead, the conduct in comparison to other medical practices—an objective analysis.

The courts do not explain the situation quite so directly, though an analysis of their opinions shows it to be the case. Many cases use the term "good faith" in explaining whether a doctor has acted "in the course of professional practice". A common sense understanding of those two words is—a mental state comprising lawful intention.[11] Other indications that a subjective element is required are shown by the Circuit's over-all explanation of the case or its direct statement about the necessity of a subjective element. Thus in the Fifth Circuit this was explained in very clear terms: "Necessarily, the issue of criminal intent or quality knowledge was a factual issue for the jury to resolve on the basis of

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[11] Most cases seem to use the term "good faith" in accord with its common sense understanding and the definition found in most other non-drug related cases. This would be the definition found in Black's Law Dictionary: "In common usage this term is ordinarily used to describe that state of mind denoting honesty of purpose, freedom of intention to defraud . . . ".

circumstantial evidence under the totality of the circumstances. It was a subjective determination." *United States v. Greenfield* 554 F.2d 179 at p. 182, 183 (5th Cir. 1977). In accord is *United States v. Guerrero* 650 F.2d 728 (5th Cir. 1981). Four other circuits, in addition to the Fifth, have decided cases where the term "good faith" or a type of specific intent at least have been mentioned.[12] Thus, for most circuits a determination at least includes a subjective component[13]—evaluating whether the doctor's intent at the time of his action was to practice legitimate medicine.

Accordingly, the conflict is made very definite and certain by the Second Circuit's ruling in this case. The ruling—which also was set forth earlier in the Statement of the Case in this Petition—was as follows: "However, this Court has recently made clear that "good faith medical practice" in the context of the federal narcotics laws is determined by objective standards and does not involve a defendant's subjective state of mind." *United States v. Vamos,* 797 F.2d 1146 1152-53 (2d Cir. 1986)." Clearly the term "good faith" has been given a different meaning in the Second Circuit than what it means in every other situation. And obviously a different, almost opposite legal standard is required of the physician in the Second Circuit.

Furthermore, the Second Circuit's position is not in keeping with prior Supreme Court rulings. While this Court has not explicitly addressed the definition of "good faith" its use has been

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[12] 6th Circuit: *U.S. v. Kirk* (infra), *United States v. Carroll,* 518 F.2d 187 (1975). 7th Circuit: *United States v. Green,* 511 F.2d 1062 (7th Circuit), *cert. denied,* 423 U.S. 1031 (1975). 8th Circuit: *United States v. Jones* (infra), *United States v. Kershman,* 555 F.2d 198 (8th Cir.) cert. denied 434 U.S. 892, 98 S.Ct. 268, 54 L.Ed. 2d 178 (1977). 9th Cir.: *United States v. Boettjer* (infra), *U.S. v. Rosenberg* (infra).

Also, it should be noted that in addition to those named in the text the 5th Circuit also mentioned the concept in *Rosen* (supra).

[13] There are cases which describe an objective feature being part of an evaluation. However, while they might not explicitly state the relationship to the subjective element, it's clear they have not done away with a requirement of a finding on the subjective element. An example is *United States v. Norris,* 780 F.2d 1209 (5th Cir. 1986).

with a subjective interpretation. Thus in the previous case before the Court on physician liability, *United States v. Moore,* (supra at p. 346), "good faith" is mentioned in describing the trial court's jury instruction and the opinion strongly implied that the term had a subjective application and meant "honest".[14] Moreover, the Supreme Court's position does not depend on a definition of "good faith". In *Moore* (supra, p. 346) it was stated that a doctor need only make an "honest effort"—obviously a subjective view—to conform with acceptable medical practices.

This lack of uniformity in the Circuits—particularly relating to so important a law that has such severe penalties—is not fair to those whom it effects and should not be allowed to stand. It is intolerable that good faith conduct of a medical professional should be lawful in one part of the country and unlawful in another, depending on the attitude of the local federal appellate court.

Conflict—Jury Instructions

The dilemma of differing standards shows itself significantly in the jury instructions. The Second Circuit flatly rejected Dr. Di Bella's contention that the jury should have been instructed to acquit unless the government proved he acted without a good faith belief that he was practicing medicine in accordance with professional standards. They in effect held instead that the lawfulness of his conduct was to be judged solely by its conformity to objective standards.

Thus the Second Circuit approved of the words "reasonably believed" to describe how a doctor's conduct should be evaluated. Those are not words that go to determining lawful intention; rather, in keeping with an objective approach for evaluation, they are words that mean the person must act in accordance with a

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[14] Among Supreme Court cases on the predecessor of Title 21 U.S.C., the Harrison Narcotics Act, one case used the term "good faith" and even quoted what it considered a satisfactory definition. This was the one used in the trial court's instruction in that case—"honestly believed". *Boyd v. United States* 271 U.S. 104, 46 S.Ct. 442, 443, 70 L.Ed. 857 (1926).

certain standard of performance, regardless of what the person might have actually believed.[15] This language is also found in the Sixth Circuit in *United States v. Voorhies,* 663 F.2d 30 (6th Cir. 1981) (though the effect of the language was not closely evaluated in that case).

In contrast, most other jurisdictions do not follow the purely objective theory created by using the words "reasonably believed" in describing "good faith". Thus one conflict exists with the eighth circuit because it is clear in that Circuit by its approval of a specific intent instruction[16] that it requires a finding on the subjective issue. *United States v. Jones,* 570 F.2d 765 (8th Cir. 1978). The issue becomes more complex upon further examination.

A complicating factor is many of the circuits indicate that juries have to be told that there are two components for the juries to consider—one, a subjective component on good faith, and two, an objective component, a following of accepted principles comprising a medical practice.[17] This then is another conflict with the purely objective theory of the Second Circuit, because the good faith element in the other circuits describes the doctor's intent. It would seem that there could be no guilty finding unless the subjective element was not found.[18] In the Ninth Circuit the distinction is clearly expressed by stating the doctor's intent

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[15] This difficulty with "reasonably" also is brought out by legal commentators. See Modern Federal Jury Instructions, Criminal, Volume 2, 1986, Sand, Siffert, Loughlin and Reiss, Matthew Bender, pp. 56-47, 56-48.

[16] The specific intent instruction is usually shown in the explanation of "willfully", and is that the person "knowingly did an act which the law forbids, purposefully intending to violate the law". *U.S. v. Hayes* (infra).

[17] These are the 5th Circuit, *United States v. Norris* (supra Ft. 13), the 7th Circuit, *United States v. Green* (supra Ft. 12), 9th Circuit, *United States v. Boettjer* (infra).

[18] The relevant Federal Regulation, Section 1306.04(a), also takes a subjective approach. This is implied by the use of the words "*his* course of practice" in the description of appropriate conduct. The Regulation is set out in Appendix C.

applies to what he believes about the patient's condition and whether he believes this is in accordance with proper medical principles.[19] *U.S. v. Hayes*, 794 F.2d 1348 (9th Circuit 1986). In accord in explaining the principle is *U.S. v. Boettjer*, 569 F.2d 1078 (9th Circuit) *cert. denied* 435 U.S. 976 (1978). Accordingly, it is certain either by using the specific intent instruction or the more clear method used by the 9th Circuit that the ultimate determination to be made is subjective—and there is a definite conflict of interpretation with the purely objective concept set forth by the Second Circuit.

Thus what has occurred is a "good faith" definition seems to have been twisted around to include action and thus been interpreted by the Second and Sixth Circuits opposite to what is the law in the other circuits. Besides the obvious unfairness of the law's interpretation in relation to a doctor's practice in the Second Circuit the additional vice of the present situation is that the breach continues and causes the boundaries to go further apart. Thus in 1981 the 6th Circuit's breach took the form of the jury instruction indicating more elaborate demands of the physician, namely, the physician had to exercise "best professional judgment" and "should" take certain action, and whatever he did must be "reasonable". *United States v. Voorhies* (supra). In other words, an objective standard that required more than average performance. In 1986 confusion worsened. In this case similar jury charges to *Voorhies* (supra) were given. However, an addi-

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[19] An instruction that is revealing in the difference between objective and subjective is provided in *U.S. v. Hayes* (infra) and is close to being correct:

"Good faith means an honest effort to prescribe for a patient's condition in accordance with the standard of medical practice generally recognized and accepted in the country. Mistakes, of course, are not a breach of good faith . . .

You need not agree with or believe in a standard practice of the profession, but must only be concerned with a good faith attempt to act according to them. Good faith is not merely a doctor's sincere intention towards the people who come to see him, it involves his sincerety in attempting to conduct himself in accordance with a standard of medical practice generally recognized and accepted in the country."

tion was made in this case—the requirement made of the doctor was elevated to the unprecedented and highest level of performance, the use of "the best" judgment. Thus the conflict became more pronounced, and the Second Circuit, by its approval, went even further in taking the law out of alignment.

Another affect is revealed by the conflict—in addition to the conflict itself—if the road of the Second Circuit is followed. *Vamos* (supra at 4902), recognized their phrasing, which was very similar to the phrasing in this case, indicates a malpractice situation. Furthermore by demanding a higher quality of treatment or more specific types of treatment or procedures from doctors, in addition to the basic features found in a medical practice, it is made even more obvious that, in effect, the dispositive phrase—course of professional practice—has been changed to mean something similar to a malpractice situation. This makes the interpretation of the conflict even more clear and also shows its far-reaching effect. The 9th Circuit in *United States v. Rosenberg*, 515 F.2d 190 (9th Circuit), *cert. denied*, 423 U.S. 1031 (1975) at pgs. 197 and 203-206 indicates that if this change were found to be the true meaning of the phrase, that would render 21 U.S.C. unconstitutional regarding health professionals. The statute would be allowing the Federal government to step outside its jurisdiction of legitimate interest in interstate commerce and encroach upon constitutional rights of states and the individual regarding medical practice. Also the 9th Circuit, *Boettjer*, (supra p. 1082) forcefully states that holding the physician to malpractice (average) standards would be "contrary to the letter and spirit of the statute."

Also it should be pointed out that the interpretation of law doesn't just effect what is told the jury. Of course what is told the jury is extraordinarily important,[20] but the meaning of the law effects every other part of the proceeding. For example Rule of Evidence 704(b) indicates that an expert is not to comment on a defendant's state of mind. Rule 704(b) then—as happened in this

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[20] As the court stated in Sandstrom v. Montana 442 U.S. 510, 61 L.Ed. 39, 99 S.Ct. 2450, at p. 53 "an unconstitutional jury instruction on an element of the crime can never constitute harmless error."

case—is ignored because "good faith" doesn't deal with a person's state of mind and is only concerned with an objective evaluation. Consequently, the expert, over objection, is allowed to testify using those terms in his explanation.

Thus the interpretation of the law effected many aspects of the case, and indicates once again why it is necessary for the conflict between the circuits to be resolved.

Conflict in Evaluation of Criteria

The Second and Sixth Circuits' erroneous instructions are not the only problem. There is a further problem and closely related conflict in determining the sufficiency of the evidence.

If an objective standard is to be involved, whether as the governing standard or as an adjunct to an unlawful intent element, how is evidence to be evaluated using that standard? An objective basis would seem to mean the absence of certain very basic features that are fundamental qualities common to every physician's legitimate medical practice when prescribing a controlled substance drug. Those features are, it is submitted, a work-up of the patient by an examination and a history, and a diagnosis. Thus, in making this determination the fact-finder would compare the questioned activity with what is done in every physician's practice and if that standard was not met, then the person could be found guilty. Similarly, if the standard was met then the person should be found not guilty. (For a guilty finding it still, it is submitted, would be necessary to find the physcian did not act in good faith.) In addition, perhaps this objectively premised concept may be followed up—thus an evaluation should be made by giving weight to incidents which may or may not take place in relation to the physician's interaction with the patient. Those incidents that are inappropriate would be termed non-physician-like features, and, most often, would be interpreted as indicative of a wrongful intent, or at the least, not what is done by the physician who is appropriately treating a patient whose treatment may call for a controlled substance drug. Examples of these non-physician-like features are talked about in the cases. Thus in *Rosen*, 582 F.2d 1032 (5th Cir. 1978) *Rosenberg* (supra) and *Moore* (supra) it was indicated that false or inaccurate records

were kept. Another example is that in Rosen (supra) and Rosenberg (supra) a street term was used in the discussion between the doctor and the patient. A problem exists as to which features may be non-physician-like and what weight to give to their occurrence. A review of cases was made and two tables listing the potentially non-physician-like features that courts have noted may be found in the appendix, Part E.[21]

All the dozens of cases reviewed showed a combination of non-physician-like features. Each summarized which of the non-physician-like features were found at trial, and each stated whether or not these medically inappropriate actions provided adequate objective evidence for a guilty finding, in light of other aspects of the case. Most cases concluded that adequate evidence had been presented. Somewhat different were two circuits that were very instructive because they revealed a perspective of when the evidence was not sufficient. Thus the evidence was thought to be "very weak" and "marginal" in *Guerrero* (supra), p. 739,

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[21] Table I incorporates the following three elements: one, the features listed by the Supreme Court in *United States v. Moore* (supra), and two, features taken from the only appeals court that researched cases from before and after 21 U.S.C. appeared, and then composed its own table, *United States v. Rosen,* (supra) and three, features which are mentioned in a representative sample of cases.

The other cases in Table I are *United States v. Vamos* (supra), *United States v. Norris* (supra ft. 13), *United States v. Voorhi s* (supra), *United States v. Guerrero* (supra), *United States v. Rosenberg* (supra), *United States v. Badia*, 490 F.2d 296 (1 Cir. 1973), *U.S. v. Bartee*, 479 F.2d 484 (10th Cir. 1973), *United States v. Boettjer* (supra).

Table 2 gives the four Supreme Court cases that explicated what the Court thinks is the objective part of the proof regarding "outside the course of professional practice"—and these are essentially either when the physician acts like a salesman to a known addict or when the physician fails to give a treatment logically related to a patient's present condition (other than any addiction): *Jin Fuey Moy v. United States,* 254 U.S. 189, 194, 41 S.CT. 98, 65 L. Ed. 214 (1920).

The other cases in Table 2 are: *United States v. Moore* (supra), *Webb v. United States,* 249 U.S. 96, 39 S.Ct. 217, 63 L. Ed. 497 (1919) *Behrman v. United States,* 258 U.S. 280, 42 S.Ct. 303, 66 L. Ed. 619 (1922).

wherein the judgment was reversed, and "extremely marginal" in *United States v. Jones,* (supra, at p. 770) where, again, the judgment was reversed. This was the conclusion even though both cases showed at least three of those non-physician-like features.

In several cases the defendant physician's behavior seemed to present the appearance of a true practice, but it was noted to be a sham because of a number of the non-physician-like features were present. *United States v. Hooker* 541 F.2d 300 (First Cir. 1976) and *Rosen* (supra) at p. 1035.

In complete opposition—and thereby creating a conflict—to all other circuits, the Second Circuit in the instant case determined evidence was adequate without even one of the non-physician-like features present. Thus, the instant case was unprecedented and took the law in the wrong direction. Furthermore, this is such a significant deviation that it shows a vagueness in the law because there is not a clear definition of what makes up the crime and therefore the law is unconstitutional due to lack of due process under the 5th Amendment.

III

CERTIORARI SHOULD BE GRANTED BECAUSE THERE ARE CONFLICTS BETWEEN THE CIRCUITS IN REGARD TO WHAT IS THE ACTION THAT IS UNLAWFUL

There is an additional problem that an objective interpretation of the law has created. A view of the indictment helps understand the difficulty.[22] Dr. Di Bella was charged and prosecuted for distribution by putting together in one count the prescriptions he allegedly wrote while he was associated with Jorum; in a second count were placed the prescriptions he wrote subsequent to

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[22] Counts 8 and 9 of the Indictment, those parts which are relevant to this case, are set out in Appendix D.

leaving Jorum.[23] Now the indictment may not be the problem,[24] however, a problem definitely is created when—as in the instant case—the judge fails to tell the jury that they had to examine each act of prescribing, or even just one act of prescribing, to see if the particular prescription had been written with an unlawful intent. No prior case has failed to hold that a requirement is that the government has to prove a specific illegal prescription or patient recipient of an illegal prescription.[25] The Sixth Circuit is instructive: "Another essential element in these counts is that a prescription was issued to a specific person in each count, unlawfully and knowingly for the purpose of distributing controlled substances as classified by Section 812, 21 U.S.C. . . ." *United States v. Kirk,* 584 F.2d 773, 786 (6th Cir. 1978). That is to say, whether or not the prescribing was unlawful must be applied to each and every prescription.[26] Finally, we are unable to find any

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[23] In actuality—in an apparent further effort to emphazise numbers and therefore an inference of guilt by the size of the numbers—all the "dosage units" were put together in each count for a particular time period. In this manner the largest number could be made. It never was shown at trial as to what a dosage unit was. Presumably, it means one pill of methoqualone.

[24] It usually is considered merely a charging document notwithstanding the psychological impact it may have on the perception of proof or its effect on the presentation of the evidence.

[25] In fact, the violation was more egregious. Over objection—a request made prior to trial—the indictment was given to the jury and it stated that "approximately" a certain number of prescriptions were written. It doesn't need citation that the theory of criminal law is not that "approximately" something happened. Evidence must show beyond a reasonable doubt that, in fact, the event did occur.

Its other effect is that it implies that an examination of any single act is not necessary.

[26] The method allowed in this case by the Second Circuit is also frowned upon by the eighth circuit wherein it was stated: "However, the Government sought to imply wrongdoing on the physician's part from the quantity of the prescriptions and the "quality" of some patients. The evidence lacked substantial probative force upon the issue of improper medical practice in the transactions charged, yet it could have led the

case where each count was not charged on a single prescription or patient.

Clearly the Second Circuit by allowing this case to stand, is in conflict with the Sixth Circuit. There is no authority for the Second Circuit's apparent view that all the prescriptions together—and therefore conduct being measured in relation to that aggregate—may form an unlawful act. Obviously their form of an objective interpretation of the law denies due process and creates confusion. What they have effectively done is allow someone to be convicted of a crime without providing the fact-finder the definition of what specific act constitutes the crime. Although the propaganda ploy by the prosecution worked at trial, the conflict it creates should not let it go unheeded.[27]

CONCLUSION

Thus a writ of certiorari should be granted.

Respectfully submitted

NICOLAS M.W. DI BELLA
Attorney of Record

(Appendices follow)

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jury to speculate that the quality of prescriptions alone established wrongful conduct by Dr. Jones". *Jones,* (supra) p. 769. (It would seem that impropriety is precisely what the prosecution engaged in doing in this case).

[27] The further problem in this case was that the actual proof did not consist of attempting to prove any particular prescription was wrongful, and yet that is exactly what is supposed to be done for each prescription written.

Appendix A

United States Court of Appeals
for the Second Circuit

At a stated term of the United States Court of Appeals for the Second Circuit, held in the United States Courthouse in the City of New York on the 19th day of November, one thousand nine hundred and eighty-six.

Present:

Hon. Ellsworth A. Van Graafeiland,
Hon. Lawrence W. Pierce, *Circuit Judges,*
Hon. Morris E. Lasker, *District Judge.**

86-1224, 86-1303, 86-1342

United States of America,
Appellee,

vs

Dr. Manuel Sanchez-Acosta, Dr. Geoffrey Di Bella,
and Dr. Irving Greenfarb,
Defendants-Appellants

ORDER

[Filed Nov. 19, 1986]

Appeal from judgments of conviction in the United States District Court for the Southern District of New York (Goettel, J.). Appellants Sanchez-Acosta, DiBella, and Greenfarb were convicted of the illegal distribution of methaqualone (more commonly known by its trade name, "Quaalude") in violation of 21 U.S.C. §§ 812, 841(a)(1) & 841(b)(1)(B). Appellant Greenfarb was also convicted of conspiring to violate federal narcotics laws under 21 U.S.C. § 846.

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* Hon. Morris E. Lasker, Senior Judge, United States District Court for the Southern District of New York, sitting by designation.

1. Appellants allege that there was insufficient evidence to establish that they were dispensing medication in bad faith. Appellants contend that in their best judgment they believed that their patients were suffering from sleep disorders and that Quaalude was the proper remedial medication. Appellants also allege that they were practicing in good faith because they were advised by competent counsel that their activities were legitimate.

When reviewing the sufficiency of the evidence, we must draw all reasonable inferences, and resolve all issues of credibility in favor of the Government. Glasser v. United States, 315 U.S. 60, 80 (1942); United States v. Martino, 759 F.2d 998, 1002 (2d Cir. 1985). The totality of the evidence adduced at trial clearly supports the jury's verdicts of guilt in this case. Each of the defendants wrote Quaalude prescriptions for more than 95% of their patients; patient examinations were very brief (usually lasting only five minutes), while the fees were quite high ($150 to $200 per visit); and further, expert testimony indicated that the medical operation was a sham. The evidence was therefore sufficient to support the verdicts.

2. Apropos appellants' argument that the prosecutor's misconduct deprived them of a fair trial, a criminal conviction will not be overturned on review unless the prosecutor's misconduct caused substantial prejudice to the defendants in the case. United States v. Biasucci, 786 F.2d 504, 514 (2d Cir.) (citations omitted), *cert. denied*, 107 S. Ct. 104 (1986). Here, appellants basically rely on two incidents to support their claim of prosecutorial misconduct. One, an altercation between the prosecutor and defense counsel, occurred outside the presence of the jury and therefore could not have resulted in prejudice. The second involved a remark before the jury, made on the first day of the month-long trial, which could be interpreted as inferring that defendant Gourji's attorney could be indicted. (Gourji did not appeal.) The prosecutor said: "You are not a defendant yet, sir." The district court immediately struck the remark from the record and chastised the prosecutor, the prosecutor apologized twice for the comment, and thereafter the district court cautioned the jury to disregard the remark. These actions eliminated any substantial

prejudice to the defendants. See United States v. Bagaric, 706 F.2d 42, 58 (2d Cir.), *cert. denied*, 464 U.S. 840 (1983).

Although we find that the prosecutor's actions did not result in substantial prejudice to appellants so as to deprive them of a fair trial, we agree that the prosecutor's outbursts and conduct were highly improper and inappropriate. Accordingly, we direct that the record herein be forwarded to the Committee on Grievances of the United States District Court for the Southern District of New York for its review of the prosecutor's conduct and for whatever action it finds to be warranted.

3. Appellants also allege that the district judge's questioning of a defense expert witness deprived them of a fair trial. Federal Rule of Evidence 614(b) specifically authorizes a trial court to "interrogate a witness, whether called by itself or a party." Indeed, a trial judge has the responsibility to assist the jury in determining the truth. United States v. Bronston, 658 F.2d 920, 930 (2d Cir. 1981), *cert. denied*, 456 U.S. 915 (1982). A conviction should be reversed only when the trial judge's conduct was so partial to the prosecution that it became a factor in determining the defendant's guilt. United States v. Pisani, 773 F.2d 397, 402 (2d Cir. 1985) (citations omitted). In this case, Judge Goettel questioned the expert witnesses of the Government as well as those of the defense. The record indicates that the trial court's questions were designed to amplify and clarify the statements of the experts. While Judge Goettel may have expressed doubt as to the defense expert's testimony in the presence of the attorneys, no such opinion was expressed before the jury. Finally, the district court instructed the jury that it should not assume that the court had an opinion about the case merely because it asked questions. Thus, we hold that the appellants were not denied a fair trial.

4. Finally, appellants argue that, by allowing expert witnesses to express an opinion concerning whether the defendants engaged in a good faith medical practice, the district court violated Federal Rule of Evidence 704(b) because, appellants urge, such testimony would address "the mental state or condition of a defendant." However, this Court has recently made clear that "good faith medical practice" in the context of the federal narcotics laws

is determined by objective standards and does not involve a defendant's subjective state of mind. United States v. Vamos, 797 F.2d 1146, 1152-53 (2d Cir. 1986). Since the expert witnesses here merely expressed their opinion that the medical practice of defendants did not conform to reasonable good faith standards, Federal Rule of Evidence 704(b) was not violated. Even if it was, the abundance of other evidence in this case would render a violation of 704(b) harmless error.

We have considered the other contentions of the appellants and find them to be without merit. Accordingly, we affirm the judgments of conviction.

/s/ ELLSWORTH A. VAN GRAAFEILAND
Hon. Ellsworth A. Van Graafeiland

/s/ LAWRENCE W. PIERCE
Hon. Lawrence W. Pierce
Circuit Judges

/s/ MORRIS E. LASKER
Hon. Morris E. Lasker,
District Judge

N.B.: Since this statement does not constitute a formal opinion of this court and is not uniformly available to all parties, it shall not be reported, cited or otherwise used in unrelated cases before this or any other court.

Appendix B

Order of United States Court of Appeals
On Petition for Rehearing
and Suggestion for Rehearing En Banc

United States Court of Appeals
for the Second Circuit

At a stated term of the United States Court of Appeals, in and for the Second Circuit, held at the United States Courthouse, in the City of New York, on the 15th day of January, one thousand nine hundred and eighty-seven.

Filed: January 15, 1987

No. 86-1224

United States of America
Appellee,

against

Dr. Geoffrey Di Bella,
Defendant-Appellant.

A petition for rehearing containing a suggestion that the action be reheard en banc having been filed herein by counsel for the defendant-appellant, Dr. Geoffrey Di Bella,

Upon consideration by the panel that heard the appeal, it is

Ordered that said petition for rehearing is denied.

It is further noted that the suggestion for rehearing has been transmitted to the judges of the Court in regular active service and that no such judge has requested that a vote be taken.

Appendix C

The pertinent part of 21 U.S.C. 841 is:

(a) Except as authorized by this subchapter, it shall be unlawful for any person to knowingly or intentionally—(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance;

The pertinent part of 21 U.S.C. 822:

(b) Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances are authorized to possess, manufacture, distribute, or dispense such substances (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

The pertinent parts of 21 U.S.C. 802 are:

(8) the terms "deliver" or "delivery" mean the actual, constructive, or attempted transfer of a controlled substance, whether or not there exists an agency relationship.

(10) the term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance. The term "distributor" means a person who so delivers a controlled substance.

(20) The term, "practitioner" mean a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital or other person . . . permitted, by the United States . . . to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or ~~r~~research.

(21) The "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

21 C.F.R. Section 1306.04(a) provides:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. Section 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Appendix D

COUNT EIGHT

The Grand Jury further charges:

Between on or about November 10, 1981, and on or about February 18, 1982, at the 34th Street Clinic in the Southern District of New York, DR. GEOFFREY DiBELLA, the defendant, unlawfully, intentionally and knowingly did cause to be distributed and dispensed, outside the scope of professional medical practice, approximately 33,240 dosage units of Quaalude (Methaqualone), a Schedule II (now a Schedule I) controlled drug substance.

(Title 21, United States Code, Section 812, 841(a)(1), 841(b)(1)(B) prior to amendment on October 12, 1984, by Public Law Number 98-473, Title 11, Section 502; Title 18, United States Code, Section 2).

COUNT NINE

The Grand Jury further charges:

Between on or about March 1, 1982, and on or about June 30, 1982, at 60 East 42nd Street, New York, New York in the Southern District of New York, DR. GEOFFREY DiBELLA, the defendant, unlawfully, intentionally and knowingly did cause to be distributed and dispensed, outside the scope of professional medical practice, approximately 5812 dosage units of Quaalude (Methaqualone), a Schedule II (later a Shedule I) controlled drug substance.

(Title 21, United States Code, Section 812, 841(a)(1), 841(b)(1)(B) prior to amendment on October 12, 1984, by Public Law Number 98-473, Title 11, Section 502; Title 18, United States Code, Section 2).

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Appendix E

Table I

Non-physician-like features pointing to guilt in 11 cases.

SYMBOLS: X = Questionable action took place.
Space is blank = was not reported.

A = Affirmed.
R = Reversed.
PR = Prescrip
PT = Patient
Px = Meeting with Patient

	Vmos	Nor	Voor	Guer	Rsen	Rbeg	Mor	Badi	Bart	Boit	DiBella
	A	A	A	R	A	A	A	A	A	A	A
Counts 1 Count = 1 PR or 1 PT	13	15	49	12	25	27	40			7	0 per PR or PT
No Px or >0.5 min.	?	X	X	X	X	X	X	X	?	X	
PT told Dr. he misued or sold it			X	X	X	X		X	X	X	
Dr. gave as asked	X	X	?	X	X	X	X	X	X	X	
No medical history	?	X	?		X	essen-tially 0		X	short/ brief only	X	Insomnia
Street term used			X	X	X	X			X	X	
Gave Rx for 5 or more pills/ day, or way too large a dose	X			X	X	X		X			X

Table I — (Continued)

	Vmos	Nor	Voor	Guer	Rsen	Rbeg	Mor	Badi	Bart	Boit	DiBella
Dr. advised PT not to get attention from pharmacist					X				X		
Dr. acting like a sales-man and/or (fee/pill)	X		?		X	X	X	X			
Ignored lab tests done							X				
No instruc-tions how to use Rx		X		X	X		X				
False or inaccurate records	X			X	X	X	X				
Undercover agents reported adversely	?	X	X	X	X	X	?	X	X	X	
TOTAL INAPPRO-PRIATE	4	5	3	7	11	9	7	5	7	5	0

Table II

Non-physician-like features pointing to guilt in 5 cases.

SYMBOLS: X = Questionable action took place. Space is blank = was not reported.

A = Affirmed.
R = Reversed.
PR = Prescrip
PT = Patient
Px = Meeting with Patient

	Behr	Moy	Moore	Webb	DiBella
	A	A	A	A	A
Counts 1 Count = 1 PR or 1 PT		20	40		(2) 0 per PR or PT
No Px or >0.5 min.		X	X		
PT told Dr. he misued or sold it	X	X			
Dr. gave as asked			X	X	
No medica/ history				X	Insomnia
Street term use(					
Gave Rx for 5 or more pills/ day, or way too large a dose	X		X	X	
Dr. advised PT not to get attention from pharmacist		X			
Dr. acting like a sales- man and/or (fee/pill)	X	X	X		
Ignored lab tests done			X		
No instruc- tions how to use Rx	X	X	X	X	
False or inaccurate records		X	X	X	
Undercover agents reported adversely			?		
TOTAL INAPPRO- PRIATE	4	6	7	5	0

No. 86-1488

In the Supreme Court of the United States

OCTOBER TERM, 1986

GEOFFREY A. DI BELLA, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

CHARLES FRIED
Solicitor General
WILLIAM F. WELD
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QUESTIONS PRESENTED

1. Whether the district court properly instructed the jury with regard to the element of intent in a prosecution of a physician for unlawfully dispensing drugs.

2. Whether the indictment properly included a number of prescriptions for drugs in a single count.

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In the Supreme Court of the United States

OCTOBER TERM, 1986

No. 86-1488

GEOFFREY A. DI BELLA, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the court of appeals (Pet. App. A1-A4) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on November 19, 1986. A petition for rehearing was denied on January 15, 1987 (Pet. App. A5). The petition for a writ of certiorari was filed on March 11, 1987. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Following a jury trial in the United States District Court for the Southern District of New York, petitioner was convicted on two counts of distribution of methaqualone, in violation of 21 U.S.C. 841(a)(1).[1] He was sentenced to

[1] Petitioner was acquitted on the conspiracy count. He had been indicted along with seven co-defendants. All eight were charged with

concurrent terms of two years' imprisonment, to be followed by a two-year term of special parole, and he was fined $5,000.

The evidence at trial established that petitioner was involved in the operation of sham medical clinics that dispensed prescriptions for Quaalude under the guise of treating stress or sleep disorders.[2] The clinics were begun by a Dr. Martin Feit, who started a "stress clinic" in his Staten Island office in early 1981 (Tr. 1406, 1866-1869). He recruited another doctor, co-defendant Greenfarb, to join him in writing Quaalude prescriptions (Tr. 1411). The clinic was forced to close in the summer of 1981 because people in the neighborhood complained that the customers were selling drugs outside the clinic (Tr. 585, 1412, 1870). Feit and Greenfarb then moved the business to Manhattan, where it flourished and expanded to additional locations. More doctors were hired, including petitioner. Tr. 504, 1220, 1266-1267, 1413, 1417-1418.

The clinics functioned ostensibly as legitimate medical practices, but it was clear from the actual operation of the clinics that their sole purpose was to sell as many

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conspiracy as well as various counts of distribution of methaqualone. Petitioner was tried with co-defendants Irving Greenfarb, Manuel Sanchez-Acosta, and Ariz Gourgi. Greenfarb was convicted on the conspiracy count as well as on two separate counts of distribution of methaqualone. Sanchez-Acosta was convicted on one count of distribution and acquitted on the conspiracy count. Gourgi was convicted on two substantive counts and acquitted on the conspiracy count. Three other defendants pleaded guilty; one remains a fugitive.

[2] "Quaalude" is the trade name for methaqualone. It is a hypnotic drug, which during the period at issue in this case was classified as a Schedule II controlled substance; it could be prescribed as a sleeping pill. Because of the widespread abuse of the drug, methaqualone has since been reclassified as a Schedule I controlled substance. As such, it may not lawfully be prescribed for medical purposes. 21 U.S.C. 829.

Quaalude prescriptions each day as possible, to virtually anyone who could pay the high fees. For example, although physical examinations were conducted, they were done entirely by physician's assistants, not by any of the medical doctors (Tr. 391). Staff members testified that urine samples were sometimes discarded without being analyzed, and that doctors prescribed Quaalude without even looking at the patients' electrocardiograms (Tr. 399, 1407). Patient history forms were completed, but they often contained patently false or inconsistent information, and simply recited boilerplate responses to indicate that the "patient" had sleep problems (Tr. 389, 871, 2113; GXs 20077, 20078, 20406, 40417, 40570). A doctor would typically spend about five to ten minutes with each client, and almost invariably write him or her a prescription for Quaalude, for a fee of $150 to $200 in cash (Tr. 1132-1133, 1139, 1355, 1364).

Most clinic doctors, including petitioner, were paid a flat rate of $2,000 to $3,000 per day; co-defendants Greenfarb and Sanchez-Acosta were paid on a per patient basis of $20 or $40 for each prescription written. Records maintained by the clinics showed that all the doctors wrote Quaalude prescriptions for more than 90% of the patients they saw; petitioner wrote Quaalude prescriptions for 98.7% of the clients he saw (Tr. 166-170; GX 3). Over one 27-day period of seeing clients, petitioner wrote 771 Quaalude prescriptions, or an average of almost 30 per day. He failed to prescribe Quaalude for only eight customers he saw during that period (GX 3).

Two undercover agents from the Drug Enforcement Administration visited the clinics in 1981 and 1982. On December 3, 1981, one agent, using the name "Michael Bates," received a Quaalude prescription from petitioner after paying $200 in cash. Two weeks later the same agent, using an entirely different name, again saw petitioner and received another prescription. He was never questioned

about using different names. Tr. 1126, 1132-1133, 1135, 1139-1140. The other agent had a similar experience on two different visits, one week apart, with co-defendant Greenfarb (Tr. 1354-1359).

The government was also assisted in its investigation by a physician, Dr. Gregory Drezga, who agreed to accept a job at one of the clinics (Tr. 1645). On the first day of his employment, Dr. Drezga saw a patient who had previously received a Quaalude prescription from Dr. Greenfarb. Dr. Drezga, however, refused to give the patient a Quaalude prescription, but instead offered her a mild form of tranquilizer, Dalmane. The patient became extremely upset and refused to pay for her visit to the clinic. Tr. 1656, 1819-1825. When Dr. Drezga made it clear to the operators of the clinic that he would not prescribe Quaalude indiscriminately, he was asked to leave the clinic (Tr. 1658; GX 19). The same patient returned to the clinic on three subsequent occasions and was given Quaalude prescriptions, twice by petitioner and once by Greenfarb (Tr. 1826-1828; GXs 2397, 4134, 3001E, 3003N).

Three witnesses who were qualified as experts on sleep disorders and the use of sedatives testified that no good faith medical practice was being conducted at the clinics. They based their conclusions on several factors: the huge volume of prescriptions, the very short time spent with each patient, and the superficial nature of the notations on the patients' charts (Tr. 870, 2106); the fact that virtually none of the patients had been referred by other physicians, when just the opposite would be typical at a bona fide sleep clinic (Tr. 875, 2109-2110); the fact that the clinics' patients included very few older people, for whom sleep problems are quite common, and that the majority of the patients were in age groups in which Quaalude abuse is common (Tr. 893, 2125-2126); and the lack of any other treatment for sleep problems, when a variety of treatments are commonly recommended, such as psychotherapy or

behavior modification (Tr. 868, 2118). In fact, the experts testified that Quaalude is rarely prescribed as a treatment for sleep disorders, and that the defendants prescribed it indiscriminately and inappropriately in many cases (Tr. 862-863, 2077, 2108, 2131).

Each of the defendants testified. Each claimed that he had acted in good faith and had prescribed medication for what he believed were legitimate medical problems.

ARGUMENT

1. Petitioner contends (Pet. 11-20) that he was improperly convicted of illegally dispensing drugs because an erroneous standard of criminal intent was used to determine whether he had dispensed the drugs in the course of good faith medical treatment. He argues that the district court erred by giving an instruction under which the jury could have convicted him without regard to his subjective intent, based solely on an objective evaluation that petitioner's practice did not conform to accepted medical practices. He also claims that the use of an erroneous standard of intent caused the court of appeals to err in its evaluation of the sufficiency of the evidence. In fact, the instruction on intent correctly stated the law, and there is no doubt that the evidence in this case was sufficient to support the jury's verdict.

a. Petitioner takes issue with the following instruction (Pet. 7; Tr. 3528):

> "If a doctor dispenses a drug in good faith in medically treating a patient, [then the] doctor has dispensed the drug for a legitimate purpose in the usual course of medical practice; that is, he has dispensed a drug lawfully.
>
> Good faith in this context means good intentions and the honest exercise of the best professional judgment as to the patient's needs. It means the doctor

> acted in accordance with what he reasonably believed to be proper medical practice."

Petitioner argues that this instruction allowed the jury to ignore his subjective intent and to convict on the purely objective determination that his conduct in dispensing drugs was not in keeping with generally accepted medical practice.

Petitioner does not point to any instruction in which the jury was told that it could convict without regard to criminal intent. The instruction quoted above requires proof that the defendant was not acting with "good intentions" and in "the honest exercise of the best professional judgment." It therefore explicitly required proof of subjective intent.

Petitioner focuses on the words "reasonably believed" in the instruction and argues that those words convert the instruction from one requiring proof of subjective intent to one permitting conviction under an objective standard of liability. But the reference to "reasonable belief" in the quoted instruction did not have that effect at all. Rather, that term was used in conjunction with the reference to the standard of proper medical practice, in order to make clear to the jury that a physician is required to know of, and to conform to, accepted norms of medical practice when prescribing controlled substances. As the court of appeals made clear in its earlier decision in *United States* v. *Vamos,* 797 F.2d 1146, 1152 (1986), cert. denied, No. 86-936 (Jan. 12, 1987), the term "proper medical practice" refers to an objectively ascertainable standard of conduct deemed appropriate by the medical community, not to the idiosyncratic views of particular physicians. That standard of conduct is derived from the regulation governing the authority of physicians to prescribe controlled substances. The regulation, and the applicable statute, 21 U.S.C. 829, grant physicians a limited exemption from the general prohibition against distribution of controlled substances,

as long as the prescription is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. 1306.04(a). The regulation adds that an order "purporting to be a prescription issued not in the usual course of professional treatment" is not a "prescription" within the meaning of the stautory exemption for physicians. *Ibid.*

The court of appeals, both in this case and in *Vamos,* was referring only to what constitutes accepted medical practice when it stated that an objective standard is to be applied. There is no suggestion that the defendant physician's intent to commit a crime is irrelevant; the court's point was simply that the physician's own particular view of what is accepted medical practice does not control that aspect of the legal standard. If the rule were otherwise, a physician could too readily avoid the strict limitations that Congress sought to impose on the medical application of Schedule II substances, simply by asserting a belief—no matter how unreasonable—that the substance in question could properly be prescribed for a variety of medical conditions. See *United States* v. *Moore,* 423 U.S. 122, 138-145 (1975). The standard applied by the court of appeals is not one of strict liability: even if the physician's conduct is outside the scope of proper medical practice, the physician is protected from criminal liability if he believes he is acting according to proper medical standards, as long as that belief is reasonable. In light of the stringent restrictions imposed on the prescription of controlled substances, there is nothing improper about holding physicians to that modest standard. As the court of appeals noted in *Vamos,* "[t]o permit a practitioner to substitute his or her views of what is good medical practice for standards generally recognized and accepted in the United States would be to weaken the enforcement of our drug laws in a critical area" (797 F.2d at 1153).

The instructions given in this case do not conflict with any of the formulations approved by other courts of appeals. Petitioner alleges that there is a conflict between this case and decisions from several other circuits, claiming that those courts apply a subjective rather than an objective standard of liability for physicians charged with unlawfully prescribing controlled substances. This contention is incorrect for two reasons. First, as we have noted, the court in this case did not subscribe to an objective test for the element of intent. The defendant must be shown to have intended to distribute controlled substances and to have done so other than in a good faith effort to provide legitimate medical treatment. The court applied an objective standard only to the extent that it required that the physician's belief that he is engaged in proper medical practice be a reasonable one. Second, the other court of appeals decisions on which petitioner relies do not reject this approach. The Fifth Circuit, in *United States* v. *Greenfield,* 554 F.2d 179, 182 (1977), cert. denied, 439 U.S. 860 (1978), simply noted the general point that the inquiry into intent is a subjective one; the court did not suggest that the defendant's belief that he was engaged in proper medical practice could not be judged according to a test containing an objective as well as a subjective component. Indeed, a more recent Fifth Circuit case specifically approved a jury instruction on the issue of the defendant's belief regarding standard medical practices that contained both subjective and objective components. See *United States* v. *Norris,* 780 F.2d 1207, 1209 (5th Cir. 1986); accord *United States* v. *Voorhies,* 663 F.2d 30, 33-34 (6th Cir. 1981).[3]

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[3]Most of the other court of appeals cases cited by petitioner (Pet. 13 n.12, 15-16) as conflicting with the decision in this case do not even address the question of whether the test for determining the defendant's adherence to proper medical practice is in part an objective one. We are aware of no case in which a court of appeals has reversed a conviction because of a charge like the one given in this case, or even

b. Petitioner also claims that the court of appeals used a standard for assessing the sufficiency of the evidence that conflicts with decisions from other circuits. This claim is entirely without merit. The court below summarized the evidence briefly in finding that the evidence was quite clearly sufficient, and its review was very similar to that undertaken by other courts in like cases. Petitioner contends that the court of appeals failed to consider any of the "non-physician-like features" of petitioner's practice. In fact, the court of appeals considered the very type of factors urged by petitioner. The court observed that prescriptions for the same medication were written for more than 95% of petitioner's patients; the court referred to the very brief patient examinations and extremely high fees; and the court noted the expert testimony explaining that the medical operation was a sham (Pet. App. A 2). The court of appeals could have detailed the facts more elaborately, but it found that unnecessary in light of the abundant proof that petitioner was not engaged in a bona fide medical practice.

2. Petitioner also complains (Pet. 20-22) that he was charged in each count with the writing of numerous prescriptions, and that the evidence failed to prove that

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criticized such a charge. The Ninth Circuit has criticized a charge that could be read to suggest that a physician would be liable if he failed to act in accordance with recognized medical standards, but that charge did not contain the proviso that the physician would not be liable if he reasonably believed he was acting in accordance with such standards, as did the charge in this case. See *United States* v. *Boettjer*, 569 F.2d 1078, 1082 (9th Cir.), cert. denied, 435 U.S. 976 (1978). Subsequent to *Boettjer*, the Ninth Circuit approved and endorsed an essentially objective standard when it approved a jury instruction which said that prescribing a controlled substance to a narcotic addict who did not have a medical complaint other than addiction or withdrawal would not constitute the good faith practice of medicine. *United States* v. *Hayes*, 794 F.2d 1348, 1352 (9th Cir. 1986), cert. denied, No. 86-848 (Feb. 23, 1987).

each specific prescription was unlawfully written.[4] He claims a conflict in this respect with the Sixth Circuit's decision in *United States* v. *Kirk,* 584 F.2d 773, cert. denied, 439 U.S. 1048 (1978), in which the court stated that an "essential element in these counts is that a prescription was issued to a specific person in each count, unlawfully and knowingly for the purpose of distributing controlled substances" (*id.* at 786).

First, petitioner failed to raise this issue below and therefore may not raise it here. *Berkemer* v. *McCarty,* 468 U.S. 420, 443 (1984); *United States* v. *Lovasco,* 431 U.S. 783, 788-789 n.7 (1977). Moreover, to the extent his complaint is that the indictment was duplicitous, his failure to raise the claim before trial constitutes a waiver. Fed. R. Crim. P. 12(b)(2) and (f); *United States* v. *Lartey,* 716 F.2d 955, 968 (2d Cir. 1983).

In any event, it was not improper for the indictment to group large numbers of prescriptions together in each count. Petitoner's course of conduct at each clinic represented a single, continuing scheme. It therefore was not necessary to charge each act of writing a prescription in a separate count. None of the dangers commonly posed by duplicitous indictments was present here: inadequate notice of the charges, exposure to the risk of double jeopardy, prejudicial evidentiary rulings, and the risk of conviction by a non-unanimous verdict. *United States* v. *Robin,* 693 F.2d 376, 378-379 (5th Cir. 1982); *United States* v. *Berardi,* 675 F.2d 894, 897-899 (7th Cir. 1982).

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[4] Petitioner was charged in Count Eight with having unlawfully dispensed, between November 10, 1981, and February 18, 1982, at the 34th Street Clinic, "outside the scope of professional medical practice, approximately 33,240 dosage units of Quaalude." In Count Nine he was similarly charged with dispensing "approximately 5812 dosage units of Quaalude" at another clinic, between March 1, 1982, and June 30, 1982. Pet. App. A8.

The approach used in the indictment in this case, in which each count of the indictment alleged a pattern of prohibited conduct, did not create a conflict with the Sixth Circuit's decision in *United States* v. *Kirk, supra.* In that case, each of the counts to which the court of appeals was referring alleged a single illegal prescription. Obviously, the proof at trial in *Kirk* had to conform to those specific allegations. Because the Sixth Circuit was not addressing a case in which a pattern of unlawful conduct had been charged in each count, the passage from which petitioner quotes cannot be read to suggest that charging in that fashion would be improper.

In this case, in contrast with *Kirk,* it was alleged that all of the prescriptions for Quaalude issued by the defendants in the course of their operation of the named clinics were unlawful, because the clinics were not operated as genuine medical practices and were actually just outlets for illegal drug distribution. The proof at trial showed exactly that. The records maintained by the clinics and the testimony of staff and "patients," undercover agents, and several expert witnesses all established that none of the Quaalude prescriptions was issued for a bona fide medical purpose, because no true medical practice was being operated. In light of the allegations and corresponding proof in this case, there was no need for the jury to focus on each particular prescription and determine whether it was unlawfully written. The evidence was sufficient for the jury to find that petitioner unlawfully dispensed as many Quaalude prescriptions as the records showed he wrote at the "stress clinics."

CONCLUSION

The petition for a writ of certiorari should be denied.
Respectfully submitted.

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